## REMARKS/ARGUMENTS

In response to the Final Office Action mailed October 10, 2007 and the Advisory Action mailed December 17, 2007, Applicants amend their application and request reconsideration in view of the amendments and the following remarks. In this amendment, Claims 1and 8 are amended, claims 13 and 14 were previously cancelled without prejudice so that Claims 1-12 currently pending. No new matter has been introduced.

Claims 1-12 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of copending application no. 10/260,632. Claims 1-12 were provisionally rejected on the ground of nonstatutorty obviousness-type double patenting as being unpatentable over claims 11-20 of copending application no. 10/431,059. Claims 1-12 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of copending application no. 11/149,466. Claims 1-12 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of copending application no. 11/244,903.

Applicants understand that these rejections are to alert Applicants that an actual rejection on the same ground may be issued if one of the applications ultimately issues. However, in light of the potential amendments to the claims of the present invention and any potential amendments made to the claims of the cited applications, Applicants shall defer any arguments and/or actions until the applications actually issue.

Claims 1-12 were rejected as being unpatentable over WO 01/87372A1 to Kopia et al (Kopia) in view of U.S. Patent Publication No. 2022/0188277 to Roorda et

al (Roorda) and further in view of U.S. Patent No. 4,743,327 to DeHaan et al. (DeHaan). This rejection is respectfully traversed.

The MPEP, in section 706.02(j), sets forth the basic criteria that must be met in order to establish a *prima facie* case of obviousness:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In *re Vaeck*, 947 F.2d,488,20 USPQ2d 1438 (Fed.Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.

Section 2143.03 of the MPEP clarifies certain criteria in section 706.02(j).

> "To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In *re Royka*, 490F.2d 981, 180 USPQ 580 (CCPA 1074). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In *re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In *re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)."

Kopia discloses a device and method for the treatment of restenois utilizing two drugs for release from a stent. One drug is rapamycin and the other possible choices include dexomethasone, growth factors, cytokine signal transduction inhibitors, anti-

proliferative drugs as well as other agents. Kopia discloses a polymeric material for affixing the drugs. Kopia does not disclose the use of topcoats.

Roorda discloses medicated stents for the treatment of vascular disease. More specifically, Rooda discloses bioactive agents for treating restenosis. Roorda discloses the use of polymeric agents for affixing the agents to the delivery device.

DeHaan discloses the use of fluropolymers.

None of the references, whether taken alone or in combination, disclose or even suggest the subject matter of independent claims 1 and 8.

In making the rejection, the Examiner states that "Clearly, one skilled in the art would have assumed the combination of the two individual agents well-known to treat vascular disease into a single composition would give an additive effect in the absence of evidence to the contrary." Applicants respectfully disagree.

Claims 1 and 8 now clearly indicate that the rapamycin and 2-methoxyestradiol potentiate or have a synergistic effect each others anti-restinotic effect by downregulating both smooth muscle cell and immune cell proliferation by distinct mechanisms. In addition, the concentration range of 2-methoxyestradiol is given.

There are many drugs for treating similar or the same disease states. However, it is not obvious or reasonable in the art to simply state that two drugs will have a synergistic effect now documented in the specification. There must be some suggestion, motivation or evidence. None of the references even disclose the combination.

In a Memorandum dated May 3, 2007 from Margaret A. Focariono, Deputy Commissioner for Patent Operations, it is stated that "in formulating a rejection under 35 U.S.C. § 103(a) based upon a combination of prior art elements, it remains

necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed."

Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Applicant would be willing to interview the present case if the Examiner so desires.

A favorable Action on the merits is earnestly solicited.

Respectfully submitted,

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